UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,705	01/28/2002	Haruki Yamada	082368-000000US	1019

20350 7590 09/08/2005

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,705	YAMADA ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *5-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4-15-02 + 7-6-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on 6-17-2005 is acknowledged. Claims 1-2 and 8 have been amended. Claim 11 has been added.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 3-3-1999. It is noted, however, that applicant has not filed a translation of the certified copy of said application. Consequently, the priority date of 3-3-2000 will be used with regard to the availability of art under 35 U.S.C 102.

Specification

The use of the trademark Tween 80 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Information Disclosure Statement

The information disclosure statements filed on 4-15-2002 and 7-16-2004 have been considered. Initialed copies are enclosed.

Election/Restrictions

Applicant's election with traverse of Group I in paper filed on 3-17-2005 is acknowledged. The traversal is on the ground(s) that the examiner has misapplied the test for unity of invention and that the independent claims avoid the art. This is not found persuasive because the examiner contends that the special technical feature of a vaccine is the antigen that induces the protective response. Moreover, contrary to Applicant's assertion, the independent claims are not free of the art (see below).

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-15 are pending. Claims 5-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 1-4 are currently under examination.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 10/363,484. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are drawn to adjuvants comprising hydroxyl unsaturated fatty acids wherein said fatty acids have 18 carbon atoms that have a trihydroxy-monoene structure.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 are rendered vague and indefinite by the use of the term "derivative thereof'. It is unclear what is meant by said term. What constitutes a "derivative"? What core structure must be maintained in order for a molecule to be considered "a derivative" instead of an unrelated molecule? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 4 is rendered vague and indefinite by the use of the phrase "prepared from a medicinal plant". It is unclear how said limitation can be met when the claimed fatty acid is synthesized (chemically) as required by claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Lederer et al. (J. Agric. Food Chem. 1999, Vol. 47, pages 4611 –4620).

Lederer et al. disclose an 18 carbon hydroxyl unsaturated fatty acid with the structure (trihydroxy-monoene) recited in claim 3 (see STIC search report, attached). The use of the descriptive term "adjuvant" is deemed to be an intended use and hence does not constitute a claim limitation. Consequently, Lederer et al. anticipates all the limitations of the rejected claims.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamberg et al. (Plant Physiology, 1996, Vol. 110, pages 807-815).

Hamberg et al. disclose an 18-carbon hydroxyl unsaturated fatty acid with the structure (trihydroxy-monoene) recited in claim 3 (see STIC search report, attached) wherein said fatty acid was isolated from *Avena sativa* seed homogenates. The use of the descriptive term "adjuvant" is deemed to be an intended use and hence does not constitute a claim limitation. Consequently, Hamberg et al. anticipates all the limitations of the rejected claims.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyaichi et al. (Natural Medicines 1995, Vol. 49 No. 1, pages 24-28).

Miyaichi et al. disclose an 18-carbon hydroxyl unsaturated fatty acid with the structure (trihydroxy-monoene) recited in claim 3 (see STIC search report, attached) wherein said fatty acid was isolated from *Sparganii rhizoma*. The use of the descriptive term "adjuvant" is deemed to be an intended use and hence does not constitute a claim limitation. Consequently, Miyaichi et al. anticipates all the limitations of the rejected claims.

Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Quinton et al. (Tetrahedron Letters, 1991, Vol. 32, No. 37, pages 4909-4912).

Quinton et al. disclose an 18 carbon hydroxyl unsaturated fatty acid with the structure (trihydroxy-monoene) recited in claim 3. The use of the descriptive term "adjuvant" is deemed to be an intended use and hence does not constitute a claim limitation. Consequently, Quinton et al. anticipates all the limitations of the rejected claims.

Conclusion

No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is 571-272-0866. The examiner can normally be reached on M-Thu 7:00 am - 5:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

ROBERT A. ZEMAN
PATENT EXAMINER

September 5, 2005